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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,092	10/19/2001	S. Rao Cherukuri	24222-X2	6756

7590 01/27/2004

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,092

Applicant(s)

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 19-28 and 31-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-18, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of response, to the office action of 07/25/03, and corrected drawings filed 10/27/03.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-13, 16-18, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krishnamurthy (US 5,508,043).

Krishnamurthy discloses a controlled release matrix that comprises active agents (abstract, column 3, lines 3-5) such as anti-histamines, analgesics, anti-inflammatory agents, gastro-intestinals and anti-emetics, anti-epileptics, vasodilators, anti-tussive agents and expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, bronchodilators, anti-inflammatory steroids, antibiotics, psychotropics, anti-diarrheals, mucolytics, sedatives, decongestants, laxatives, antacids, vitamins, stimulants and appetite suppressants (column 7, lines 34-56). The controlled release matrix comprises pharmaceutically acceptable sodium alginate (abstract and column 3) and for tablets and caplets, the matrix also contains generally accepted pharmaceutical lubricants and waxes or fats, magnesium stearate and calcium phosphate (column 6, lines 16-37 and 59-63 and examples 9-11).

The prior art, Krishnamurthy is directed to a controlled release matrix that employed as a delivery matrix for a number of drugs including psychotropic drugs. Krishnamurthy does not exclude any psychotropic agent and thus the matrix of Krishnamurthy can be used with all

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psychotropic drugs. Fluoxetine is a psychotropic drug. Thus regarding instant claim 8, Fluoxetine-HCl, a psychotropic drug, can also be used with the matrix of the prior art.

Krishnamurthy discloses the caplet composition of the instant claims except that Krishnamurthy is silent on the dimension of the capsule. However, caplets by their nature and design have dimensions of length and diameter and it is within the purview of one of ordinary skill in the art to be able to measure the length and diameter of the caplet. However, it appears to the examiner that the dimensions of the caplet does nothing additional to the caplet dosage form since there is no comparable example to demonstrate that the diameter or length of the caplet provides unusual results. Regarding instant claims 4 and 5, one can substitute one erodible polymer with another with the expectation that the polymer will have controlled release properties. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the caplet dosage form of Krishnamurthy where the dosage form comprises active agent, lubricant and sodium alginate. One having ordinary skill in the art would have been motivated to measure the diameter and length of the caplet in order to determine the dimensions of the caplet.

Response to Arguments

3. Applicants' arguments filed 10/27/03 have been fully considered but they are not persuasive.
4. Applicants argue that Krishnamurthy uses a combination of sodium alginate and calcium salt while in the instant claims a "list of water soluble and water insoluble erodible polymers" can be used. It is noted that claims 3 and 5 while providing lists of water-soluble and water insoluble erodible polymers also selects one from the list provided and as such the prior art only

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needs to teach one of the erodible polymers recited in the said claims. Also the argument that the calcium salt in the prior art is essential for cross-linking with the alginate is an argument for intended use in a composition claim, the requirement is that the prior art teach the composition and in this case the prior art does. Regarding the argument over the size of the instant caplet, there is no demonstration that the specific size recited for the caplet provides unusual results or characteristics over the caplet of Krishnamurthy in light of the fact that all caplets, by virtue of the unique shapes have certain dimensions of length and diameter. In the absence of a showing of criticality, the dimensions recited for the instant caplet is not inventive over the caplet of Krishnamurthy

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600

